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(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) Utility services. The design must provide for continued operation of essential utility services.

(8) Inspection, testing, and maintenance. The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(9) Criticality control. The design must provide for criticality control including adherence to the double contingency principle.

(10) Instrumentation and controls. The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Facility and system design and facility layout must be based on defense-in-depth practices.[1] The design must incorporate, to the extent practicable:

(1) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and

(2) Features that enhance safety by reducing challenges to items relied on for safety.

§ 70.65 Additional content of applications.

(a) In addition to the contents required by § 70.22, each application must include a description of the applicant's safety program established under § 70.62.

(b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary), but shall not be incorporated in the license. However, changes to the integrated safety analysis summary shall meet the conditions of § 70.72. The integrated safety analysis summary must contain:

(1) A general description of the site with emphasis on those factors that could affect safety (*i.e.*, meteorology, seismology);

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to § 70.62(c)(1)(i)–(iii) and a general description of the types of accident sequences;

(4) Information that demonstrates the licensee's compliance with the performance requirements of § 70.61, including a description of the management measures; the requirements for criticality monitoring and alarms in § 70.24; and, if applicable, the requirements of § 70.64;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing each item relied on for safety which is identified pursuant to § 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of § 70.61;

(7) A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in § 70.61(b)(4) and (c)(4);

[1] As used in § 70.64, Requirements for new facilities or new processes at existing facilities, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and

(9) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

§70.66 Additional requirements for approval of license application.

(a) An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied with the requirements of §§70.21, 70.22, 70.23, and 70.60 through 70.65.

(b) Submittals by existing licensees in accordance with §70.62(c)(3)(i) will be approved if the Commission determines that:

(1) The integrated safety analysis approach is in accordance with the requirements of §§70.61, 70.62(c)(1), and 70.62(c)(2); and

(2) The schedule is in compliance with §70.62(c)(3)(ii).

(c) Submittals by existing licensees in accordance with §70.62(c)(3)(ii) will be approved if the Commission determines that:

(1) The requirements of §70.65(b) are satisfied; and

(2) The performance requirements in §70.61 (b), (c) and (d) are satisfied, based on the information in the ISA Summary, together with other information submitted to NRC or available to NRC at the licensee's site.

§70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (*e.g.*, expiration date) of the change; and

(6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with §70.62.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with §70.34.

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change:

(1) Does not:

(i) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of §70.61 and that have not previously been described in the integrated safety analysis summary; or

(ii) Use new processes, technologies, or control systems for which the licensee has no prior experience;

(2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary;

(3) Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and

(4) Is not otherwise prohibited by this section, license condition, or order.

(d)(1) For changes that require preapproval under §70.72, the licensee